DATE OUT: 06/AUG/2008

FEE: PRODUCT CHEMISTRY REVIEW OF: AN End-Use Product [X]
DP BARCODE:D340594 RECEIVED DATE:13/JUN//2007 FILE SYMBOL: 264-RNAT
PRODUCT NAME: SC 480 Herbicide FOOD USES [X]
COMPANY NAME: Bayer CropScience LP.MRID.: 471140-22C ACTION CODE:R01.0
PPC# OF THE TGAI IN THIS PRODUCT: 123000 DECISION No.: 379124

FROM: Sami Malak, Chemist
Technical Review Branch/RD (7505C)

TO: 23 Joanne Miller/James Stone
Herbicide Branch/RD (7505C)

INTRODUCTION:

In a letter dated 09/MAY/2007, the applicant requested registration of subject product. In support of this application, the applicant included product chemistry data, a proposed basic CSF dated 22/JAN/2007, a proposed label EPA received on 11/MAY/2007, Certificate With respect to Citation of Data, and data Matrix.

FINDINGS:

1. The subject product was produced by an non-integrated formulation system, meaning that the active ingredient in the product is registered. The product 20.34% isoxaflutole, Reg. No. 264-566 (98% on the label, 98.5% on the CSF). In addition, the product contains [redacted] cyprosulfamide as a safener.

2. The subject product, a herbicide, is intended for weed control in field corn in certain states cited on the label.

3a. The applicant should be advised to submit the results of product's storage stability (GRN 830.6317) and corrosion characteristics (GRN 830.6320), when complete.

3b. Except for the data gaps in Finding 3(a) above, the submitted product chemistry data is adequate and support registration of subject product.

4a. Adequate analytical methods are available for enforcement. The method for isoxaflutole was previously submitted and reviewed in connection with its registration, Reg. No. 264-566.

4b. A HPLC method was included with this submission, MRID #471140-22C. The method entitled "Determination of isoxaflutole and cyprosulfamide (AE 0001789) in formulations by liquid chromatography (HPLC)." The method is reviewed in this memorandum.

4c. The method in 4(b) above will need to be validated by the EPA's laboratory. The applicant should be advised to submit a copy of the method and samples to EPA's laboratory for validation at the following address: EPA's Analytical Chemistry Laboratory, 701 Mapes Road, Fort Meade, Maryland 20755-5350.

5a. The label claim nominal concentration of 20.34% isoxaflutole is inconsistent with the same in the basic CSF 22/JAN/2007, 20.34% on the label as opposed to 20% on the CSF. The storage and disposal statement is in compliance with the regulations of 40CFR§156.78.

5b. For consistency with the CSF, the applicant should be advised to revise the label nominal concentration for isoxaflutole, from 20.34% to 20%.

5c. The applicant should be advised to list, in product's label, a statement pertaining to "The Physical or Chemical Hazards."

5d. The label ingredient statement that reads "Inert Ingredients" must be corrected to read "Other Ingredients."

6a. The proposed basic CSF dated 22/JAN/2007 was filled out correctly and completely and agree with the label claim nominal concentration as per the regulations of PR Notice 91-2. Further, the upper and lower certified limits are within the standard limits of 40CFR§158.175(b)(2).

6b. The applicant should be advised to submit the chemical name, CAS registry number, and percent of each component in an inert ingredient not approved for use in pesticide formulations intended for food uses (refer to Confidential Appendix A).

6c The safener cyprosulfamide is currently under review by the Inert Ingredient Branch and, at this time, is not approved to be used in pesticide formulations.

6d. Except for the non-cleared ingredients in Findings 6b & 6c above, the remaining ingredients claimed in the basic and alternate CSFs have been approved for use in pesticide formulations intended for food uses.

CONCLUSIONS:

After approval of the safener, cyprosulfamide, by the Inert Ingredient Branch for use in pesticide formulations plus resolving findings 3(a), 4(c), 5(b), 5(c), 5(d), and 6(b) above, the TRB will have no objections for registration of subject product. The proposed label EPA received on 11/MAY/2007 and the proposed basic CSF dated 22/JAN/2007 are unacceptable.

Note to RM:

Please note Findings 6(c) above.

REVIEW OF PRODUCT CHEMISTRY DATA (MRID #460585-01:

1. A statement of data confidentiality dated 05/JUN/2007 was included with this submission claiming confidentiality of any of the submitted data on the basis of its falling within the scope of FIFRA§10(d)(1)(A), (B), or (C). Review of this data was moved to Confidential Appendix A.

2. A GLP statement dated 08/MAR/2007 was included with this submission to the effect that some of the studies were conducted in compliance with standard laboratory and industrial practices.

830-1800 Enforcement Analytical Method:

Adequate analytical methods are available for enforcement. The method for isoxaflutole was previously submitted and reviewed in connection with its registration, Reg. No. 264-566. A HPLC method was included with this submission, MRID #471140-22C. The method entitled "Determination of thiencarbazone-methyl (BYH 18636) cyprosulfamide (AE 0001789) and isoxaflutole (AE B197278) in formulations by liquid chromatography (HPLC)."

In this method, the test substance is dissolved in acetonitrile. The samples are then placed in an ultrasonic bath for 5 minutes, diluted to the desired volume with acetonitrile and sonicated for 10 minutes. The samples are then allowed to cool to ambient temperature. Aliquots of 5 µl are then injected to the HPLC. The compounds are separated from the formulation on a reversed phase HPLC column and detected by UV with the use of external standards.

Method validation data regarding recovery, accuracy, precision, and linearity are adequate. Sample chromatograms and calculations are included with this submission.

Group A, Series 830-Product Identity, Composition, and Analysis (40 CFR 155, 160, 162, 167, 175 & 180)

830-1550 Product Identity and Composition

The product contains one registered technical grade of an active ingredient, isoxaflutole, Reg. No. 264-566. In addition, the product contains the safener cyprosulfamide plus intentionally added inert ingredients (refer to the proposed basic CSF dated 22/JAN/2007).

830-1600 Description of Materials Used to Produce the Product:
Refer to Confidential appendix A.

830-1650 Description of Formulation Process:
Refer to Confidential appendix A.

830-1670 Discussion of Formation of Impurities:
Refer to Confidential appendix A.

830-1700 Preliminary Analysis: Refer to Confidential appendix A.

830-1750 Certified Limits: Refer to Confidential appendix A.

Identity, Composition, Formulation, and Analysis, Subgroup A, Series 830.1550 to 830.1800 (40 CFR 158.155 to 158.180)

Guideline Reference NO.(GRN 830.)/Title	Data Fulfilled	MRID No.
.1550 Product identity and composition	Y	471140-22c
.1600 Description of materials used to produce the product	Y	471140-22c
.1620 Description of production process	NA	
.1650 Description of formulation process	Y	471140-22c
.1670 Discussion of formation of impurities	Y	471407-22c
.1700 Preliminary analysis	NA	
.1750 Certified limits	Y	471140-22c
1800 Enforcement analytical method	Y	471140-22c

Explanations: Y =The requirements were fulfilled; N = The requirements not fulfilled; N/A = Not applicable; G = Data gap; U = Requires upgrading; I = Incomplete or in progress; W = Waived.

Physical and Chemical Properties of Diuron Technical; 40CFR158.190

Except for product's storage stability (GRN 830.6317) and corrosion characteristics (GRN 830.6320), the submitted physical/chemical properties are adequate and support registration of subject product.

Confidential Appendix A

830-1600 Description of Materials Used to Produce the Product:

One registered technical grade of an active ingredient plus the safener cyprosulfamide and intentionally added inert ingredients.(refer to the proposed basic CSF dated 22/JAN/2007).

830-1650 Description of Formulation Process:

[redacted]

830-1670 Discussion of Formation of Impurities:

The applicant reported no impurities ≥0.1% by weight were known to be formed during formulation and storage of the product. There was no chemical reaction in the process.

830-1700 Preliminary Analysis:

Not applicable for this non-integrated product.

830-1750 Certified Limits:

The applicant reported the same certified limits as those in the proposed basic CSF dated 22/JAN/2007.

Non-Cleared Inert Ingredient for Food Uses:

[redacted]

Inert ingredient information may be entitled to confidential treatment

Manufacturing process information may be entitled to confidential treatment

cc::S. Malak and Central File (Reg. No. 264-RNAT).
7505C:RD:TRB:CM-2:Rm.268:s.m.:06/AUG/20087:703-308-9365:<264-RNAT>.